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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,989	09/10/2003	Jan Bastiaan Bouwstra	BOUWSTRA-3	6068
545	7590	06/02/2004	EXAMINER	
ANTHONY H. HANDAL KIRKPATRICK & LOCKHART, LLP 599 LEXINGTON AVENUE 31ST FLOOR NEW YORK, NY 10022-6030			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,989	<b>Applicant(s)</b> BOUWSTRA ET AL.	
	<b>Examiner</b> Anand U Desai, Ph.D.	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-12 and 14 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 8, 13 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/10/2003</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/658,989, filed on September 10, 2003. The priority date is September 11, 2002.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on September 10, 2003 is being considered by the examiner.

### ***Specification***

3. The disclosure is objected to because of the following informalities:

There are multiple instances through out the specification where the words, "amino acid" are missing a space between them, for example on page 8, lines 16, 21, and page 10, line 14. The sentence on page 9, beginning on line 4, appears to be missing the word "can" after the words "...comprising gelatins..". There is a typographical error on page 10, line 5, the word "serie" appears to be intended to be "series". The abbreviation on page 10, line 10 of IEP is undefined, suggest writing it as "isoelectric point (IEP)" at the first appearance. The words, "bloodplasma" is missing a space between the two words on page 14, line 31. The words, "bloodvessels" is missing a space between the two words on page 15, lines 3, and 4. There is a typographical error on page 22, the "4oC" in the remarks section appears to be intended to be "4°C". On page 23, line 10, the word red blood cell should be spelled out prior to using the abbreviation "rbc".

Appropriate correction is required.

Art Unit: 1653

***Claim Objections***

4. Claims 5, 7, 8, 13, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2, does the monomer protein have the molecular weight from at least 10,000 Daltons to at most 50,000 Daltons and has an isoelectric point of less than 8 or is the molecular weight and isoelectric point referring to the dimer, trimer, and tetramer?

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6, 9-12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by HAEMACCEL package insert (Effective publication date=August 28, 1992). HAEMACCEL is

Art Unit: 1653

a registered trademark pharmaceutical that is a colloidal intravenous infusion solution composed of degraded gelatin polypeptides cross-linked via urea bridges. The mean molecular mass of HAEMACCEL is 35,000 Da. The isoelectric point is  $4.7 \pm 0.3$ . HAEMACCEL is used as a plasma expander (see enclosed package insert pages 1-4, current application, claims 1-4, 6, 9-12, and 14).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4, 6, 9-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ecanow et al. U.S. Patent 4,539, 204 in view of HAEMACCEL package insert. Ecanow et al. discloses a composition of matter that comprises modified gelatin with an isoelectric point below 8. The composition can be used as a whole blood substitute (see U.S. Patent '204, claims

Art Unit: 1653

1-10). Ecanow et al. does not disclose the composition comprising a saline solution, but suggests that the composition can be made using sufficient electrolyte to achieve an isotonicity equal to that of physiological saline solution (see column 6, lines 31-45). Therefore, it would have been obvious to the person having ordinary skill in the art to prepare a modified gelatin colloid volume expander, such as HAEMACCEL, comprising a solution of saline and a gelatin-like protein (current application, claims 1-4, 6, 9-12, and 14).

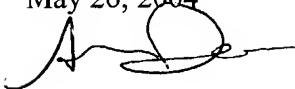
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (517) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 26, 2004



  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER